IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC., Plaintiff, v. DAIICHI SANKYO CO., LTD., *Defendant, and* ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA UK LTD., *Intervenor-Defendants*	)	CASE NO. 2:20-cv-00337-JRG [redacted]

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF ANTICIPATION

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I. SEAGEN'S PRIORITY CLAIM FAILS AS A MATTER OF LAW

Seagen concedes that "the textual disclosure of the priority applications is not in dispute." Opp. 9. The Parties agree that: (1) the Priority Applications disclose eleven categories of peptide linkers, Def. Br. 5; (2) the Priority Applications disclose more than 47 million options within the single "tetrapeptide" category, *id.* at 6; (3) the Asserted Claims are limited to ADCs with only 81 of those 47 million tetrapeptides (those using only glycine ("Gly") and phenylalanine ("Phe")), *id.* at 16; (4) *none* of the tetrapeptide examples fall within claimed subset, *id.* at 7; and (5) to the extent DS-8201 infringes, the Asserted Claims are anticipated absent a valid priority claim, *id*. at 4, 10; *see* Opp. §§ IV-V (nowhere disputing anticipation based on Seagen's infringement theory). Those agreed-upon facts legally foreclose Seagen's priority claim and mandate summary judgment of anticipation. Def. Br. 16-20; *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996).

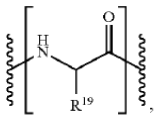
A. Seagen's "Precise Formula" Is Irrelevant

1. The "Precise Formula" Fails to Disclose Gly/Phe-Only Tetrapeptides

Seagen first argues that Defendants "ignore a crucial aspect of the claims: the recitation of a precise formula depicting the structure of the claimed compound." Opp. 9 ("an ADC having a linker unit defined by a formula '-A_a-W_w-Y_y-'"). That formula ("-A_a-W_w-Y_y-") appears in both the Priority Applications and Asserted Claims, *id*., but it is not all the claims require. The disputed limitation—restricting the linker ("W_w") to a *tetrapeptide consisting only of Gly and Phe*—is not present in this "precise" formula and is absent from the Priority Applications. They therefore cannot support the '039 patent's claim to an earlier priority date.

The Asserted Claims require that the "—W_w—unit is a tetrapeptide"—a unit of 4 amino acids, one of the many categories of amino acid units disclosed in the Priority Applications. They further require that "each —W—unit is independently an Amino Acid unit" defined as follows:

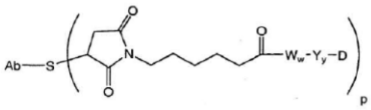
each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:

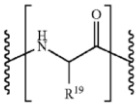


wherein R^{19} is hydrogen or benzyl,

'039 Patent (D.I. 255-01), claim 1. The Parties agree that the term "wherein R^{19} is hydrogen or benzyl" requires all four amino acids in the tetrapeptide to be Gly or Phe, Opp. 6, 10, rather than one of the many other amino acids disclosed in the Priority Applications, Def. Br. 5-6. This greatly restricts the possible linker units—where the formula "-A_a-W_w-Y_y-" in the Priority Applications would cover infinite sequences, the Asserted Claims cover a mere 81—and it is entirely *absent* from the Priority Applications. Seagen's "precise formula" does not support its priority claim.

It is thus correct and irrelevant that the Asserted Claims and Priority Applications both disclose the same ADC formula and "structure for each amino acid within the peptide unit":





Opp. 10 (citing '340 application ¶¶ 0684, 0715). Neither of these images address the key limitation that W_w must be four amino acids with R^{19} as hydrogen or benzyl at each of the four positions. That requirement comes from the words of the Asserted Claims, not a picture. And fatally for Seagen, those words are absent from the Priority Applications. Def. Br. 1-2, 15-20.

2. The Remaining "Laundry List" of Linkers is Legally Insufficient

Because its "precise formula" is silent as to the limitation at issue, Seagen relies on the broad generic disclosure of the 2004 Application (App. No. 10/983,340). Seagen argues that "Application discloses detailed information about the amino acid unit" including that "it is a dipeptide, tripeptide, *tetrapeptide*, pentapeptide . . . or dodecapeptide unit," and "states that each R^{19} side chain is selected from a group of 39 side chains." Opp. 11. That list of 39 side chains

"include[s]" hydrogen and benzyl—the side chains corresponding to Gly and Phe. *Id.*

In the tetrapeptide category *alone,* Seagen agrees this "laundry list" of amino acid side chains covers 47 million sequences. *Id.* at 9; Def. Br. 16-20. The Federal Circuit consistently has held as a matter of law that such an undifferentiated "laundry list" does not provide written description support for all possible combinations of listed items. Def. Br. at 17-20; *Fujikawa*, 93 F.3d at 1571; *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000).

Seagen's only response turns the law on its head. Seagen notes that the *claims* are "limited to only 'a minute subgenus' of those linkers: only 81 tetrapeptides, not millions." Opp. 12. This discrepancy is a *problem* for Seagen, not an asset. To satisfy the written description requirement, the Priority Applications must show the POSA that Seagen invented ADCs with the claimed set of 81 Gly/Phe-only linkers, from among the forest of 47 million tetrapeptide linkers they disclose. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997). The narrowness of the claimed set of linkers compared to the breadth of the Priority Applications' disclosure makes Seagen's conclusion *less* likely—not *more* likely, as Seagen wrongly suggests. Opp. 12.

The Federal Circuit in *Fujikawa* provided the rubric to evaluate the written description of claims that recite a chemical formula with substituents selected from a list of options in the specification. *See* Def. Br. 18. Seagen's cases—*In re Driscoll*, 562 F.2d 1245 (C.C.P.A. 1977), and *Novartis Pharms. Corp. v. Plexxikon Inc.*, PGR2018-00069, Paper 16 (P.T.A.B. Jan. 16, 2019) ("*Plexxikon*")—neither conflict with *Fujikawa* nor suggest a different result here.

The Federal Circuit clearly addressed the key distinction between *Driscoll* and *Fujikawa*, rejecting the very argument Seagen advances here: while claiming a category disclosed in the specification is permitted, claiming "only a narrow *subset*" of that category that requires multiple selections not disclosed in the specification *violates* the written description requirement. *In re*

Wako Pure Chem. Indus. Ltd., 4 F. App'x 853, 855-57 (Fed. Cir. 2001). The *Driscoll* application disclosed "fourteen distinct classes of compounds, each class" defined by a different option at a single variable. *Driscoll*, 562 F.2d at 1249. The claim in *Driscoll* recited "one of the fourteen classes of compounds." *Id.* The Federal Circuit deemed this the crucial distinction between *Driscoll* and *Fujikawa*: *Driscoll* simply required selection of a single category disclosed in the priority application in its entirety—without further subdividing it—rather than a "subset" of a category. *Wako*, 4 F. App'x at 857. Had Seagen claimed ADCs using "tetrapeptides" (the disclosed category) rather than "Gly/Phe-only tetrapeptides" (only part of it), *Driscoll* might be instructive. But Seagen agrees it did not do so. Def. Br. 5-6. Unlike *Driscoll*, Seagen's claims require first selecting 1 of 11 disclosed peptide categories (tetrapeptides), then selecting "only a narrow subset" of that category by picking and choosing among 83 options at each of four different positions to arrive at the claimed tetrapeptides. *Wako*, 4 F. App'x at 855. That further refinement, absent from *Driscoll*, is dispositive here. *Id.*; *Fujikawa*, 93 F.3d at 1371; *Purdue Pharma L.P. v. Iancu*, 767 F. App'x 918, 924 (Fed. Cir. 2019) ("laundry list" of "undifferentiated compounds" suitable for use in combination did not support claim to a specific combination); *FWP IP ApS v. Biogen MA*, 749 F. App'x 969, 977-78 (Fed. Cir. 2018) (no support where POSA "would need to pick and choose from" a "laundry list of diseases" and "numerous possible dosing schedules").

Nor does *Plexxikon*, a PTAB decision, support the indiscriminate picking and choosing Seagen urges. The Board found sufficient blazemarks leading to the claimed choices for variable "R^1" because "3 compounds disclosed in the specification . . . [fell] within the scope of the claims" and exemplified the precise combination of substituents claimed. *Plexxikon*, at *17. It was those examples (wholly absent here) that "adequately support[ed] . . . the sub-genus now claimed," *id.*—not, as Seagen contends, the mere recitation of "a Markush group of 23 substituents," Opp. 13.

B. No Blazemarks in the Priority Applications Point to the Alleged Invention

Seagen also seeks to conjure a factual dispute as to whether the Priority Applications' examples provide blazemarks to the claimed 81 ADCs with Gly/Phe-only tetrapeptides. Opp. 16-22. Seagen's arguments cannot succeed for two reasons, each of which independently mandates summary judgment. Def Br. 20-27. First, Seagen supplants the written description inquiry with an improper obviousness analysis, relying on material wholly *outside* the Priority Applications to identify other peptides the POSA would make based on their disclosure, rather than to *interpret* what the applications themselves disclose. Opp. 19-22; Def Br. 24-25. Second, even Seagen's spurious "blazemarks" admittedly identify sets of sequences that are *not* the claimed invention. Opp. 28-29; Def. Br. 25-27. Either legal flaw is sufficient to foreclose Seagen's priority claim.

1. The Applications Must Describe the Invention, Not Render It Obvious

The Priority Applications must *describe* the claimed invention, not render it obvious. Per the *en banc* Federal Circuit: "[A] description that merely renders the invention obvious does not satisfy the requirement." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1352 (Fed. Cir. 2010). "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed." *Lockwood*, 107 F.3d at 1571-72. "It is not sufficient for purposes of . . . written description . . . that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Id.* at 1572.

2. Seagen Argues the Asserted Claims are Obvious, not Described

Crucially, Seagen concedes that none of the Priority Applications' examples show Gly/Phe-only tetrapeptides. Opp. 17 (citing 2004 App. at ¶¶ 0690-91) (examples are Gly-Phe-Leu-Gly, Ala-Leu-Ala-Leu, and Gly-Ser-Val-Gln). Thus, Seagen cannot argue that the examples standing alone direct the POSA to the claimed invention—to the contrary, the examples point to

tetrapeptides that fall *outside* the Asserted Claims. Def. Br. 21 (collecting testimony).

Accordingly, Seagen can offer only obviousness arguments. *First*, Seagen argues that the POSA would have been motivated to *modify* the examples to make sequences undisclosed in the Priority Applications that fall within the claims. Opp. § V.B.1. Per Seagen, "[t]hese examples, along with other exemplary amino acid sequences, *would have guided a person of ordinary skill* to gly/phe tetrapeptides." *Id.* at 17. Critically, Seagen does not argue that the Priority Applications (beyond the unavailing broad formula discussed above) actually disclose Gly/Phe-only tetrapeptides (let alone the set of 81 claimed). Rather, Seagen argues the POSA would have selected one of the three tetrapeptide examples in the 2004 Application, and then been "*drawn to consider several modifications*" to that example "based on the disclosure of the Priority Applications and the literature on substrates for lysosomal proteases." *Id.* That is a classic "lead compound" obviousness theory, *see Otsuka Pharm. v. Sandoz*, 678 F.3d 1280, 1291-92 (Fed. Cir. 2012)—*i.e.*, the POSA "would have started their analysis" with the lead compound Gly-Phe-Leu-Gly, and been motivated to modify it ("considered substituting a [Phe]") to make Gly/Phe-only tetrapeptides, Opp. 18-19. But "[t]he question is not whether a claimed invention [ADCs with Gly/Phe-only tetrapeptides] is an obvious variant of that which is disclosed in the specification [ADCs using Gly-Phe-Leu-Gly]." *Lockwood*, 107 F.3d at 1572. "Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Id.* (affirming summary judgment of anticipation for improper priority claim); *TurboCare Div. of Demag Delaval Turbomachinery v. Gen. Elec.*, 264 F.3d 1111, 1120 (Fed. Cir. 2001) (affirming summary judgment of no written description); *PowerOasis v. T-Mobile USA*, 522 F.3d 1299, 1310 (Fed. Cir. 2008) (rejecting "expert declaration" suggesting obviousness and affirming summary

judgment of anticipation for improper priority claim). Seagen's theory fails as a matter of law.

Second, Seagen argues, Opp. § V.B.2, that prior art outside the Priority Applications and "not about ADCs" nonetheless "would have informed persons of ordinary skill how to design an ADC when read in the context of the disclosures of the [Priority Applications]," *id.* at 19. That is another obviousness theory—that the Priority Applications' disclosures, in combination with prior art, would have led the POSA to "design" the undisclosed claimed invention. Seagen asserts that the POSA would have *ignored* the ADC prior art *discouraging* tetrapeptides, and "*reevaluate[d]*" certain "*non*-ADC literature" that happens to disclose (in the context of different molecules) what the Priority Applications do not: a few Gly/Phe-only tetrapeptides. *Id.* 20-21.

Setting aside the implausibility of Seagen's convoluted assertion (which contradicts its argument, made to secure allowance, that the POSA would have eschewed non-ADC prior art, Ex. 23 at 7-9), this theory fails because it is an obviousness one as well, and also because it improperly relies on prior art outside the Priority Applications to supply the disclosure of the critical limitation. The written description "test requires an objective inquiry into the four corners of the specification from the perspective" of a POSA. *Ariad,* 598 F. 3d at 1351. The law is clear that, while "the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification." *Lockwood*, 107 F.3d at 1571 ("It is the disclosures of the applications that count."). In other words, "[t]he knowledge of ordinary artisans may be used to inform what is actually in the specification . . . *but not to teach limitations that are not in the specification*." *Rivera v. Int'l Trade Comm.,* 857 F.3d 1315, 1322 (Fed. Cir. 2017) (emphasis added).

Had the Priority Applications disclosed a Gly/Phe-only tetrapeptide limitation, but merely used different words to do so, the law would permit reliance on prior art to *interpret* that disclosure.

Id. at 1322-23; *Lockwood*, 107 F.3d at 1571. But the Priority Applications do *not* disclose Gly/Phe-only tetrapeptides, Def. Br. 16-20, and longstanding, controlling precedent precludes the prior art from "gap-filling" that missing disclosure. *Rivera*, 857 F.3d at 1322; *Lockwood*, 107 F.3d at 1571-72; *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367 n.13 (Fed. Cir. 2006).

Seagen cites no case to the contrary. *Contra* Opp. § B.3. The Priority Applications "must be read from the perspective of a person of skill in the art." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 2022 U.S. App. LEXIS 58, at *22 (Fed. Cir. Jan. 3, 2022). But no law, including *Novartis*, permits the prior art to provide description for limitations wholly absent from the Priority Applications. Indeed, the Federal Circuit expressly rejects such an approach. *Rivera*, 857 F.3d at 1322-23; *Lockwood*, 107 F.3d at 1571-72. In *Falkner*, the priority "application disclosed the use of essential genes . . . and simply did not include the well-known sequence" of that gene. *Rivera*, 857 F.3d at 1315 (citing 448 F.3d at 1366-68); *see also All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002) (claim using different words nonetheless "reflects what the specification shows has been invented"); *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1064 (Fed. Cir. 2020) (claim reciting well-known full-length DNA sequence supported where specification cited identification numbers for that sequence and prior art disclosing it). By contrast, the Priority Applications here fail to disclose ADCs with the 81 claimed tetrapeptides (from among the category of 47 million) using any words or examples, and Seagen does not allege that Gly/Phe-only tetrapeptides were "well-known" ADC linkers. To the contrary, Seagen acknowledges they appear in uncited, *non*-ADC art the POSA would have needed to "reevaluate." Opp. 19. They are not described as a matter of law. *Ariad*, 598 F.3d at 1351; *Rivera*, 857 F.3d at 1322-23; *Lockwood*, 107 F.3d at 1571-72; *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1365-66 (Fed. Cir. 2011) (rejecting reliance on prior art to supply a critical limitation, and

affirming summary judgment given the absence of disclosure or examples meeting the limitation).

3. Seagen's Blazemarks Point to the Wrong Subgenus

Seagen's theory of written description contains an independent legal flaw: the blazemarks Seagen conjures from its obviousness theories point to a subgenus that is *not* the claimed invention. Opp. 18-19 (obviousness theory including tetrapeptides with serine, leucine, valine, and alanine), 20-21 (reciting six of 81 Gly/Phe-only tetrapeptides and one tetrapeptide with leucine).

Seagen concedes that its alleged blazemarks do not point to the 81-member genus it claimed. *Id*. That ends this case. Seagen relies solely on a desperate legal argument: that Defendants' legal standard requiring that the blazemarks point to the "exact claimed subgenus" is "made-up." *Id.* at 2. It is Seagen, not Defendants, who misapprehend the law, ignoring the blackletter requirement for written description of "the invention claimed." *Ariad*, 598 F.3d at 1351 (disclosure must "show that the inventor actually invented the invention claimed"); *Bos. Sci.*, 647 F.3d at 1369 ("Given the paucity of disclosure regarding the claimed sub-genus, no reasonable juror could conclude that … the inventors were in possession of the claimed invention.").

In this context, that longstanding precedent requires, in the forest of the priority disclosure, blazemarks identifying the "invention claimed," whether it be a tree (if a single species is claimed) or trees (if a subgenus of multiple species is claimed). *Fujikawa*, 93 F.3d at 1571 ("one of ordinary skill would not be led to *Fujikawa's sub-genus in particular*" (emphasis added)); *Bos. Sci.*, 647 F.3d at 1367 ("[T]he lack of such blaze marks . . . prevents any conclusion that the patent contains sufficient written description of the *claimed [subgenus]*. No reasonable juror could determine that the specification 'reasonably convey[s] to persons skilled in the art that the inventor had possession' *of the claimed sub-genus*." (emphases added)).

The cases Seagen cites do not—and cannot—suggest that blazemarks to a single species within a claimed subgenus would be sufficient. *Contra* Opp. 29. *Novozymes* explains the

unremarkable proposition that (as here) the absence of examples within the scope of the claims tends to show lack of written description, not that, contrary to controlling law, blazemarks to a single species describe an entire subgenus. *Novozymes A/s v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013); *Ariad*, 598 F.3d at 1350; *Bos. Sci.*, 647 F.3d at 1367. And *Novartis* explained that, "where the specification describes a broad genus and the claims are directed to a single species *or a narrow subgenus*, . . . the specification must contain 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Novartis Pharms.*, 2022 U.S. App. LEXIS 58, at *5 (emphasis added). Contrary to Seagen's strained reading, the reference to "*such* a species" plainly refers to the antecedent "single species"—not a single species within a claimed subgenus.

There is no dispute that Seagen's proposed blazemarks lead to subgenuses that exclude most of the 81 claimed tetrapeptides and add other unclaimed tetrapeptides. Whatever this motley assortment reflects, it is not the claimed "*sub-genus in particular*." *Fujikawa*, 93 F.3d at 1571.

II. THE INVENTORS ADMIT LACK OF CONCEPTION AND DESCRIPTION

"[O]ne cannot describe what one has not conceived." *Falkner*, 448 F.3d at 1367 n.13. Seagen nevertheless urges the court to ignore the inventors' myriad admissions regarding lack of conception by 2004 because written description "is not based on actual reduction to practice of the claimed invention by the inventors." Opp. 23. Defendants never asserted that actual reduction to practice is required. Rather, the inventors' repeated sworn admissions that they did not conceive or describe ADCs with Gly/Phe-only tetrapeptides before 2017, Def. Br. § V.B.3—most of which Seagen does not seek to explain or erase by errata—show that they were not in possession of such ADCs in 2004 and, as a matter of law and common sense, did not then describe them either.

III. CONCLUSION

For the foregoing reasons, Defendants are entitled to summary judgment of anticipation.

Dated: January 28, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document was filed electronically UNDER SEAL and served by e-mail on January 28, 2022, to all counsel of record.

/s/ Jennifer P. Ainsworth
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[redacted]